ARDL

QUALITY MANAGEMENT PLAN

REVISION 01.3

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ACRONYMS AND ABBREVIATIONS

ANSI/ASQ	American National Standards Institute/American Society of Quality Control
ARDL	ARDL, Inc.
CAR	Corrective Actions Report
DoD-ELAP	Department of Defense Environmental Laboratory Accreditation Program
DQO	Data Quality Objectives
EPA	Environmental Protection Agency
ISO/IEC	International Organization for Standardization/International Electrotechnical Commission
ISM	Information System Manager
LAN	Local Area Network
LIMS	Laboratory Information Management System
PE	Performance Evaluation
PM	Project Manager
QA	Quality Assurance
QAPP	Quality Assurance Project Plan
QA/QC	Quality Assurance/Quality Control
QAM	Quality Assurance Manager
QAO	Quality Assurance Officer
QC	Quality Control
QMP	Quality Management Plan
SAP	Sampling and Analysis Plan
SOP	Standard Operating Procedure
TNI	The NELAC Institute
UFP-QAPP	Uniform Federal Policy for Quality Assurance Project Plans
USEPA	United States Environmental Protection Agency

1.0 INTRODUCTION

This document is the Quality Management Plan (QMP) of ARDL, Inc. (ARDL), located in Mount Vernon, Illinois. ARDL is a full service environmental firm offering laboratory testing and field services to industry as well as federal, state and local governmental agencies. This QMP is prepared following EPA QA/R-2, "EPA Requirements for Quality Management Plans", EPA/240/B-01/002 March 2001, reissued May 2006 or ANSI/ASQ E4-2014.

2.0 MANAGEMENT AND ORGANIZATION

2.1 QUALITY POLICY

Mission and Vision Statements

The mission of ARDL is to provide top quality and legally defensible analytical data in a timely and efficient manner to our customers. Our vision is to be recognized as a leader in achieving technical excellence and to be our customers' best resource. To this end, the management is dedicated to the encouragement of excellence in every aspect of our operations.

Objectives

- To provide appropriate leadership, clear vision, and focus upon core values;
- To ensure employee safety and well-being;
- To build customer service and satisfaction through customer interaction;
- To continue improvement of quality at the source, through employee involvement;
- To provide attention to data delivery deadlines and how to meet them consistently;
- To carry out all of our analytical operations in a cost-effective manner; and
- To maintain compliance to ISO/IEC 17025:2005, TNI 2009 EL-V1 "Management and Technical Requirements for Laboratories Performing Environmental Analyses" and Department of Defense Environmental Laboratory Accreditation Program (DoD-ELAP) policies.

The management system of ARDL is comprised of all of the policies and procedures in the Quality Assurance Program Plan and other referenced documents and has been established to guide the staff in the performance of good laboratory practices and the production of quality outputs. The requirements of the management system apply to all technical work conducted, in principle and in detail, to the extent possible and feasible.

ARDL intends to provide customers or other concerned parties the highest quality related to the services and data provided and is committed to meeting or exceeding the customer's requirements.

The purpose of the management system is to help fulfill the mission, vision, and objectives of ARDL. All ARDL personnel are to implement and follow the policies contained within the Quality Assurance Project Plan (QAPP), to all procedures referenced within it, and to ISO/IEC 17025:2005. Each employee has a role in ensuring the quality of ARDL's work and has a responsibility for the implementation and improvement of the management system according to his/her technical and/or managerial responsibilities.

The technical and quality management of ARDL is committed to good professional practice and compliance to ISO/IEC 17025:2005. Each member of the staff shall be alert to problems or sources of error that could compromise the quality of technical work performed throughout the laboratory. Problems or sources of error shall be reported to Managers, a Quality Assurance Officer (QAO), the Laboratory Director, Field Services Manager, or the President.

2.2 PERSONNEL RESPONSIBILITIES

Figure 1 is a representation of the present organization of the senior management and supervisory technical staff of ARDL. The duties and responsibilities of the named individuals in the figure and other positions as well are described in the text below. All members of the staff - managerial, supervisory, professional and administrative - are aware that satisfying the requirements of ARDL's quality system imposes additional demands on the manner in which they perform their daily work assignments.

President – Ms. Valerie Jenkins is President and is ultimately responsible for all aspects of the performance of the laboratory. As President, Ms. Jenkins sets the standards of quality which all laboratory operations must achieve. The President is supported in that effort by the Laboratory Director, QAO, Technical Services Manager, Environmental Field Services Manager and Business Manager, all of whom are Vice Presidents and members of the board. As shown in the figure all personnel in the laboratory report to the Laboratory Director, except for the QAO who acts independently as the administrator of ARDL's quality system.

Quality Assurance Officers – Mr. Dean Dickerson is the Laboratory QAO. Mr. Randall Jenkins is the Field QAO. They serve as the focal points for quality assurance/quality control (QA/QC) and are responsible for oversight and objective review of QC data free from outside influences. In addition, they are responsible for ensuring that all other aspects of the quality system are also in accord with the President's standards. The QAOs report directly to the President and ensure independent function outside of the command/reporting line of the laboratory and field services which move through the Laboratory Director and the Field Services Manager.

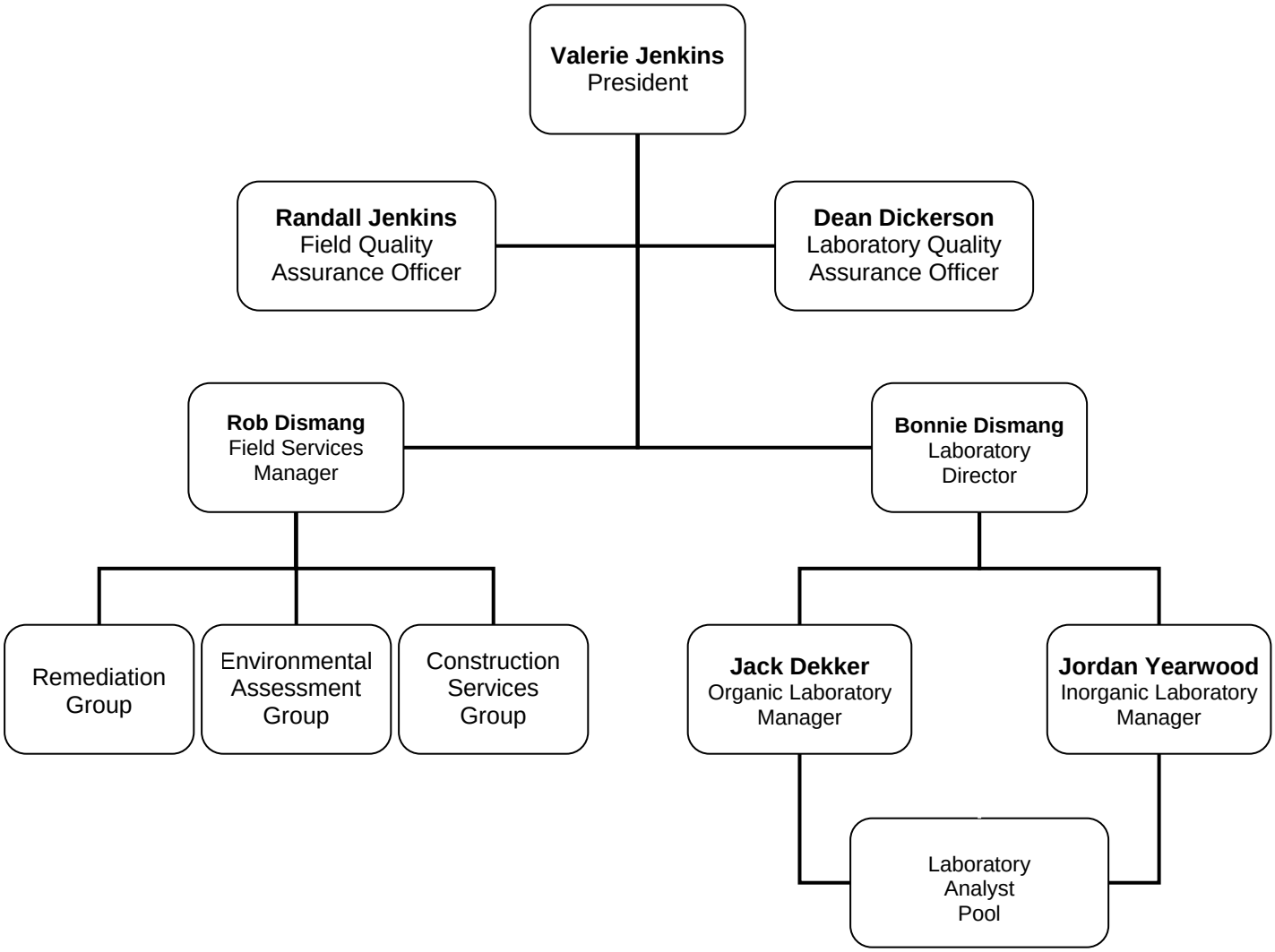
As QAO their specific duties include:

- Reporting on a regular basis to the President regarding the status of the quality system and, when appropriate, presenting recommendations relative to ways that the system may be improved.
- Reviewing the progress of analyses under way to ensure that the requirements necessary to fulfill the specifications and guidelines in the QMP and QAPP are met on a routine basis.
- Reviewing results obtained on QC determinations as well as data submitted to clients.
- Conducting internal audits of operations and data integrity training of personnel at least annually.
- Advising the Laboratory Director and Field Services Manager relative to the acceptability of QC data, coordinating with those individuals in cases where QC data are outside acceptable limits so that appropriate corrective actions may be taken and monitoring the progress of those corrective actions.
- Supervising maintenance of QC logbooks and records on a continuous basis.
- Approving standard operating procedure (SOP) documentation.
- Evaluating the procedures and practices in place relative to the requirements of the quality system.
- Assessing potential of changes in the quality system which may result in improvement.
- Reviewing the SOP's, QAPP and QMP on at least an annual basis to insure that all of those documents reflect current procedures and policies and that the objectives of the President relative to the quality system are satisfied.

The QAO operates independently of the direct command line which involves all other senior management personnel and staff members. Because of this, the President has directed that they develop a mechanism whereby employees that feel pressures are being applied to them which have a negative impact on their ability to perform their work may report the situation in a confidential, safe environment.

Laboratory Director – Ms. Bonnie Dismang is the Laboratory Director. She is directly responsible to the President for all operations in the analytical laboratory and remains available to the staff for advice and counsel as required to perform their tasks. A significant portion of the Director's time is dedicated to on-going assessment to ensure that the quality system is applied to all aspects of laboratory function. Existing policies, processes and procedures and the resources available to meet laboratory needs are subject to critical, continuing evaluation. The resources evaluated include personnel, available equipment and space.

FIGURE 1: TABLE OF ORGANIZATION



3.0 QUALITY SYSTEM COMPONENTS

ARDL requires the following:

- Each project generating environmental data will develop and implement a QAPP that addresses the required major elements and will ensure that adequate resources (both monetary and staff) are provided to support the QA/QC effort. The QAPP will specify the detailed procedures required to assure quality data. The QAO must approve QAPPs prior to data collection.
- All environmental data generated will be of known and acceptable quality as defined in the data quality objectives. The data quality information developed with all environmental data will be documented and available.
- The intended use of the data is defined before the data collection effort begins, so that appropriate QA/QC measures may be applied to ensure a level of data quality commensurate with the monitoring objectives. The determination of this level of data quality shall also consider the prospective data needs of secondary users. Data quality objectives are established to ensure the utility of monitoring data meets its intended use. The intended data uses, level of quality, specific QA activities, and data acceptance criteria needed to meet the data quality objectives are described in the ARDL QAPP.
- QA activities are designed in the most cost-effective fashion possible without compromising data quality objectives.

3.1 PRINCIPAL COMPONENTS AND TOOLS OF THE QUALITY MANAGEMENT SYSTEM

The primary QA planning and implementation components include a QMP, establishment of data quality objectives, QAPP, SOP and QA status reports. The components are listed below. Section 9 of this document discusses in detail staff responsibilities for the development of each component. Section 10 of this document covers the tools required for their implementation.

3.1.1 QUALITY MANAGEMENT PLAN

The ARDL QMP describes policies, procedures, and systems governing program specific data collection activities. It serves as the general document for QA/QC operations. The QMP will be reviewed annually by the QAO and ARDL management and revised as necessary.

3.1.2 DATA QUALITY OBJECTIVES

Data Quality Objectives (DQOs) are statements of the quality of environmental data required to support program decisions or actions. DQOs establish the level of risk or uncertainty that the program is willing to accept in the environmental data in order to make a defensible decision. The ARDL QAO uses EPA QA/G-4 “Guidance For The Data Quality Objectives Process” when developing DQOs and submitting to ARDL management for review and approval. DQOs are updated as needed to reflect changes in environmental policies as defined by management.

DQOs are intended to accomplish the following: 1) Clarify the project objectives, 2) Define the most appropriate types of data to collect, 3) Determine the most appropriate conditions under which to collect the data, and 4) Specify the level of uncertainty that is acceptable as the basis for establishing the quantity and quality of data needed.

3.1.3 QUALITY ASSURANCE PROJECT PLAN

Effective management of a data collection program requires periodic assessment of the data quality to establish a basis for determining when and if corrective action may be needed. To ensure that this assessment occurs, all environmental monitoring planned or conducted at ARDL shall have an associated QAPP.

The QAPP shall ensure that:

- The level of data quality needed is determined and stated prior to data collection.
- All environmental data generated and processed will reflect the quality and integrity established by the QAPP.

The QAO shall notify the Project Managers (PMs) immediately of any problem areas identified. The QAO will outline necessary changes and PMs will institute the corrective actions. The QAO will conduct a follow-up review of the required changes. PMs will verify that the identified problems have been corrected.

The project plan is used as a guidance document for PMs, who are responsible for the development of QAPPs for all projects conducted by ARDL. Any project plans which are developed will follow the "EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5" guidance document and be submitted to the QAO for approval prior to initiation of data collection activities.

The QAO will review and approve submitted QAPPs in the context of the program's DQOs. Reviews shall follow the QAPP review checklist listed in the "EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5" guidance document. In addition the QAPP shall follow the format of Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP). PMs will update project plans as needed and resubmit the plans to the QAO for review and approval. The QAO will review the ARDL QAPP annually and update the document as necessary. Updates will be reviewed and approved by ARDL Management.

3.1.4 STANDARD OPERATING PROCEDURES

The use of SOPs at ARDL serves as a mechanism to ensure comparability across environmental data collection projects. ARDL SOPs are incorporated into the ARDL QAPP and maintained by the QAO.

SOPs detail the work processes conducted or followed within the company. The SOPs document the way activities are to be performed to facilitate consistent conformance to technical and quality system requirements and to support data quality. SOPs are intended to be specific to the program whose activities are described and assist the program to maintain its QA/QC processes.

The best written SOPs will fail if not followed. Therefore, the use of SOPs needs to be reviewed and reinforced by the laboratory managers. Current copies of SOPs also need to be readily accessible for reference in the work area of those individuals actually performing the activity, either in hard copy or electronic format. To ensure availability, SOPs are accessible electronically on the ARDL internal network designed to provide all the necessary documents required by ARDL staff to conduct their daily operations. In addition, SOPs are also available in hardcopy, throughout the laboratory.

SOPs need to remain current. Whenever field procedures or analytical requirements are changed, the SOPs should be updated, reviewed and re-approved as soon as possible rather than waiting for an annual review. Changes or modifications may be made only to the pertinent section of a SOP, but the process must indicate the changed date and/or revision number in the document control notation.

It is the responsibility of the QAO to ensure that ARDL policies and procedures are current and any changes communicated to the staff to implement in their environmental data operations. SOPs undergo annual review to ensure any procedures not updated to reflect changes in field procedures or analytical requirements are brought up to date.

3.1.5 QUALITY ASSURANCE STATUS REPORTS

The ARDL QAPP for data collection will include the frequency, content and format of the required QA status reports. The QAO will submit QA status reports to the ARDL Management staff and these are used to help track QA progress. Whenever possible, status reports will be produced quarterly and will address the following elements if applicable:

- Changes that occurred in program activities (sampling, QC control measures, analytical methods).
- A summary of performance and system audits as they apply.
- Any corrective actions taken.
- Any organizational changes.
- Reports of the assessment of data quality indicators (precision, accuracy, completeness, representativeness and comparability).

4.0 PERSONNEL QUALIFICATION AND TRAINING

Management has developed the technical requirements of its management system recognizing that the factors in the following sections are critical in determining the correctness and reliability of tests and it has addressed these factors with policies and procedures to reduce the uncertainty of the tests performed.

The Laboratory and Field Service Managers are responsible for ensuring that all team members are competent and have received all required training prior to allowing them to work on customer samples.

The Laboratory and Field Service Managers ensure that the training, competency and authorization records of all members are current and upon completion will transfer those records to the QAO.

It is ARDL's policy that all personnel shall continuously improve the quality of their work. The process of defining individual training needs and providing that training is described in ARDL's SOP "Technical Services Personnel Training." The demonstration of competence of the staff is an ongoing activity and is monitored through the use of QC samples and proficiency testing. The data used to demonstrate analyst competency is kept in individual training records. The analyst's Laboratory Manager shall clearly authorize the analyst to conduct the tasks and tests and to operate specific equipment.

The laboratory uses personnel who are permanently employed or are under contract. When part-time employees are used their work shall be compliant with the laboratory's management system, and shall be subject to all policies and procedures regarding training and demonstration of competency.

For each position appearing on the organizational chart, the laboratory has prepared a Job Description. The job responsibilities and authorities for all personnel shall be found in their Job Descriptions.

Participation in interlaboratory proficiency testing programs serves as a tool for qualifying laboratory personnel and aids management in authorizing personnel to perform particular laboratory tasks. Where interlaboratory proficiency tests do not exist, Laboratory Managers implement intralaboratory proficiency tests as a substitute. Results of proficiency tests are maintained by the Laboratory Managers to document the performance of employees in such tests. Any corrective action taken as a consequence of the results will be documented in the training records.

Data integrity training shall be provided as a formal part of new employee orientation and shall also be provided on an annual basis for all current employees. Employees are required to understand that any infractions of the data integrity procedures shall result in a detailed investigation that could lead to very serious consequences including immediate termination, debarment or civil/criminal prosecution. The initial data integrity training and the annual refresher training shall have a signature attendance sheet or other form of documentation that demonstrates all staff have participated and understand their obligations related to data integrity.

Data integrity training requires emphasis on the importance of proper written narration on the part of the employee with respect to those cases where data may be useful, but are in one sense or another partially deficient. The topics covered in such training shall be documented in writing (such as an agenda) and provided to all trainees. At a minimum, the following topics and activities shall be included:

- Organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting, how and when to report data integrity issues, and record keeping;
- Training, including discussion regarding all data integrity procedures;
- Data integrity training documentation;
- In-depth data monitoring and data integrity procedure documentation; and
- Specific examples of breaches of ethical behavior such as improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards.

The data integrity procedures may also include written ethics agreements, examples of improper practices, examples of improper data manipulations, requirements for external ethics program training, and any external resources available to employees.

5.0 PROCUREMENT OF ITEMS AND SERVICES

5.1 APPLICABILITY

These requirements apply only to those ARDL procurement actions or suppliers who provide services or items that directly affect the quality of results or products (e.g., analytical laboratory services, sample collection or sampling plan preparation) for environmental projects.

5.2 QA REQUIREMENTS

All contracted services or products that eventually yield environmental data will require, as a QA requirement, a QMP/QAPP by the provider or prospective provider of the services or products.

The QMP/QAPP will be reviewed by an ARDL QAO to assure compliance with the customers' requirements for both data quality and completeness. After approval of the QMP/QAPP, all data collected and submitted from contracted sources will be reviewed and approved by a QAO prior to use at ARDL. All PMs and purchasing agents will ensure only approved sources are used.

6.0 DOCUMENTS AND RECORDS

Provisions for control of documentation which was either internally generated or received from an outside agency to become part of or act in support of ARDL operations are described in the current revision of the SOP's entitled "Document Control" and "General Policies." Some of the key concepts and procedures relative to this matter which appear in the referenced documents are discussed briefly in the following text.

6.1 CONTROLLED DOCUMENTS

A master list of documents controlled by ARDL is maintained. The list contains names, sources, revision numbers, location and other identifiers as appropriate.

6.1.1 INTERNALLY PREPARED

Controlled documents and their revisions must be prepared and approved by cognizant members of the senior management or supervisory staff and must be distributed to personnel following a fixed protocol. Examples of controlled documents generated in the laboratory are:

- SOPs for laboratory methods (analytical and prep);
- SOPs for field operations;
- SOPs for collection, evaluation and charting of QC data;
- The QAPP; personnel training plans; etc.;
- Spreadsheets, graphs, tables, flow diagrams and other aids used in sample analysis.

6.1.2 RECEIVED FROM OUTSIDE SOURCES

Examples of externally generated documents which appear on the master list of controlled documents are:

- Photocopies and/or originals of analytical or preparative methods;
- Operator manuals for instruments or software;
- QMP/QAPPs of clients, policy statements and/or standards of accreditation bodies;
- Spreadsheets, graphs, tables, flow diagrams and other aids used in sample analysis.

6.2 CONFIDENTIAL DOCUMENTS

A confidential document is any paper or collection of papers containing data or other information which is the property of a specific individual or organization. Confidential documents of clients may not be revealed to any other party unless release is specifically authorized by the client. Confidential documents of ARDL may not be revealed to another party unless the release is authorized by a member of senior management. Some examples of confidential documents are:

- Reports or data packages containing or discussing analytical methods or results generated for clients;
- Papers received from clients discussing or describing technical matters relative to work which was or will be proposed to them or is already in progress;
- Papers related to business matters regarding work which was or will be proposed to clients or is already in progress; papers related to business at ARDL including any matters associated with personnel;
- Internal policy statements relative to new or revised procedures for handling samples, data, client information and other sensitive subjects.

6.3 PUBLIC PAPERS

Public papers are prepared by ARDL specifically for dissemination of information concerning the capabilities of the laboratory and the qualifications and experience of the staff. Examples of such documents are certifications issued to ARDL by regulatory and other agencies, detailed statements of laboratory capability, results of performance evaluation (PE) samples received from vendors, sales brochures describing ARDL's facilities, etc.

7.0 COMPUTER HARDWARE AND SOFTWARE

The exchange of data between ARDL, our subcontract laboratories, and our customers is vital to many of ARDL's projects. ARDL utilizes a Laboratory Information Management System (LIMS) which was designed to store all the laboratory data, and a vast majority of the field data, generated by ARDL. The databases of this LIMS were designed, and have been specifically tailored, to allow for the gathering, organizing, storing and reporting of the environmental data collected by ARDL for their customers.

The Information System Manager (ISM) is responsible for managing ARDL's technology infrastructure and components. The ISM controls user credentials for employees requiring access to ARDL computer systems. He also maintains records of all computer components on the system, to include location systems type, software resident, and other information.

All information management system development, improvements, and updates are submitted to a group consisting of ARDL personnel from the division that generates and utilizes the data. The tasks are prioritized and given to the ISM for implementation. Prior to implementing changes in the infrastructure or components, they are thoroughly tested by the ISM to ensure these changes perform as expected and meet the user requirements.

To ensure compatibility with existing programs, the ISM reviews and installs all software and hardware purchases within ARDL.

8.0 PLANNING

8.1 SYSTEMATIC PLANNING COMPONENTS

The elements of systematic planning include:

Organization: Identification and involvement of the PM, project personnel, technical personnel, QAO and stakeholders.

Project Goal: Definition of the project goal, objectives, study questions, and issues.

Schedule: Identification of the project schedule, resources (including budget), milestones and any applicable requirements (e.g. regulatory or contractual requirements).

Data Needs: Identification of the type of data needed and how the data will be used to support the project’s objectives.

Criteria: Determination of the quantity of data needed and specification of performance criteria for measuring quality.

Data Collection: Description of how and where the data will be obtained (including existing data) and identification of any constraints on data collection.

Quality Assurance: Specification of needed QA/QC activities to assess the quality performance criteria (e.g. QC samples for field and laboratory, audits, technical assessments, performance evaluations, etc.)

Analysis: Description of how the acquired data will be analyzed (either in the field or the laboratory), evaluated (i.e. QA review/verification/validation) and assessed against its intended use and the quality performance criteria.

8.2 SYSTEMATIC PLANNING STEPS

Systematic planning for environmental data operations shall be guided by the seven step process described below.

Step 1 – Problem statement – Define the problem that necessitates the study; identify the planning team (typically the PM, technical personnel, QAO and stakeholders), examine budget and schedule.

Step 2 – Identify goals of the study – State how the environmental data will be used in meeting objectives and solving the problem; identify study questions, define alternative outcomes.

Step 3 – Identify information inputs – Identify data and information needed to answer study questions.

Step 4 – Define the boundaries of the study – Specify the target population and characteristics of interest, define spatial and temporal limits and scale of interest.

Step 5 – Develop the analytical approach – Define the parameter of interest, specify the type of inference and develop the logic for drawing conclusions from findings.

Step 6 – Specify performance or acceptance criteria – Specify probability limits for false rejection and false acceptance decision errors for decision making (hypothesis testing) and develop performance criteria for new data being collected or acceptable criteria for existing data being considered for use.

Step 7 – Develop the plan for obtaining the data – Select the resource-effective sampling and analysis plan (SAP) that meets the performance criteria.

8.3 QUALITY ASSURANCE PROJECT PLAN

The QAPP may be prepared by the PM or his designee. Except where specifically delegated in the QMP of the US Environmental Protection Agency (USEPA) organization sponsoring the work, all QAPPs prepared by non-USEPA organizations must be approved by USEPA before implementation.

The QAPP shall be reviewed and approved by an authorized USEPA reviewer to ensure that the QAPP contains the appropriate content and level of detail. The authorized reviewer, for example the USEPA PM with the assistance and approval of the USEPA Quality Assurance Manager (QAM) or by the USEPA QAM alone, are defined by the USEPA organization's QMP. In some cases, the authority to review and approve QAPP is delegated to another part of the USEPA organization covered by the same QMP. In cases where the authority to review and approve QAPP is delegated in writing by USEPA to another organization (i.e., a Federal agency or a State under an USEPA-approved QMP when the environmental data operation itself has been delegated to that organization for implementation), it is possible that the USEPA PM and USEPA QAM may not be involved in the review and approval steps.

Because of the complex and diverse nature of environmental data operations, changes to original plans are often needed. When such changes occur, the approving official shall determine if the change significantly impacts the technical and quality objectives of the project. When a substantive change is warranted, the originator of the QAPP shall modify the QAPP to document the change and submit the revision for approval by the same authorities that performed the original review. Only after the revision has been received and approved (at least verbally with written follow-up) by project personnel, shall the change be implemented.

In all cases, the QAPP should follow the requirements of EPA QA/R-5 and the UFP-QAPP format.

9.0 IMPLEMENTATION OF WORK PROCESSES

This section of the QMP provides directions and guidance regarding the preparation, approval, revision, issue and control of documents which describe the standard practices and procedures for performing routine environmental operations at ARDL.

9.1 NECESSITY OF SOPs

SOP documentation is needed for virtually all technical and some critical administrative activities at ARDL so that:

- Those activities can be performed effectively and efficiently and in an approved manner by any qualified member of the staff who has been adequately trained; and
- Customers, regulatory agencies and other interested parties can be assured that the practices in use in the laboratory satisfy whatever requirements may be imposed on them.

An effective SOP document defines all aspects of an operation by:

- Describing the purpose of the effort;
- Outlining the steps required and also noting any problems which may be encountered as the work proceeds;
- Itemizing equipment, materials or other items which will be needed during performance of the work;
- Detailing the exact steps involved in performing the task; and
- When necessary, providing criteria by which the quality of the result obtained from the effort may be assessed.

9.2 DETERMINATION OF NEED

Determination that an SOP document is required for a routine operation is made at the management level either unilaterally or in response to a need identified by a knowledgeable member of the staff or by an outside party such as a customer or regulatory entity. Determination of need is usually, but not necessarily, associated with an end date when the document will be completed and ready for issue by cognizant ARDL personnel.

9.3 ASSIGNMENT OF RESPONSIBILITY

Once that determination is made, an individual or group of individuals thoroughly familiar with the objectives of the task at hand is assigned responsibility for generation of the document. When technical matters are involved, personnel knowledgeable with the theory and practices associated with those matters are always included in the preparation of the document.

9.4 REVIEW AND APPROVAL

Cognizant technical supervisory, management personnel, and the QAO review finished technical SOP documents. Once consensus is reached regarding the language in the document, the document is read by all technical personnel who will perform the work described. Those individuals sign and date a statement that the text has been read and understood and that they agree to follow the procedures described in the document.

When all reviews are complete and the agreement page has been executed a member of the management staff signs the title page to indicate that the document has been reviewed and approved and is ready for issue.

If there are technical aspects to the procedure described in the document, the review process includes the QAO who signs the title page to indicate that the document has been reviewed and approved and is ready for issue.

9.5 ISSUE AND DISTRIBUTION

The document control clerk distributes copies of the document in accordance with the provisions of the most recent revision of the SOP for document control. Individuals, to whom copies are issued, sign and date a receipt. If the document replaces an older version, standard procedure requires collection of outdated documents. A temporary exception is granted for technical SOPs when work involving the previous version is in progress. When that work is complete, the outdated documents are collected. After collection, all copies are destroyed with the exception of one hardcopy which is archived and one electronic copy which is stored as a read-only document on the local area network (LAN).

9.6 REVIEW AND REVISION

All SOPs are reviewed at least annually by technical supervisory and management personnel. That interval may be shortened occasionally in response to a specific need of a customer, issue of a revision of the parent method or procedure, acquisition of new instrumentation or other event which requires a procedure change.

As a result of review, changes in procedure may appear to be required. Once consensus regarding the proposed revision is reached, the new document is approved and distributed as described in Sections 9.4 and 9.5, above.

Occasionally, the individuals performing the activity described in an approved document will identify an approach or technique which improves upon the procedure. If a supervisor or manager agrees with the suggested change, they sign and date a handwritten notation in the approved document as temporary permission to use the suggested modification. As soon as practicable, the change is incorporated into a new revision of the document which is then approved and issued as described in Sections 9.4 and 9.5, above.

10.0 ASSESSMENT AND RESPONSE

In order to ensure that QA plans are being implemented and are adequate for their intended purpose, technical and managerial assessments are necessary. These assessments, provided by internal audits, represent a mechanism of oversight for QA activities used at ARDL.

10.1 INTERNAL AUDITS

Internal audits may be of four general types: 1) system audit; 2) performance audit; 3) method audit; or 4) quality audit. Such audits are performed at least annually by the QAO or, in some instances, by designated alternates. This section describes the objectives of these audits and the procedures to be followed when they are conducted.

10.2 INTERNAL AUDITOR QUALIFICATIONS

Personnel performing internal audits must have the formal education and experience necessary to understand the technical and / or the administrative systems which will be reviewed. Documentation of those qualifications will be taken from personnel files and employee training records.

10.3 TECHNICAL AUDITS

10.3.1 SCOPE AND OBJECTIVES

Internal system audits consist of reviewing the procedures used in performing both administrative and technical functions. The audits will consist of an evaluation of:

- Readiness of personnel to perform the work required;
- Adequacy and condition of the facilities, equipment and materials available for that work;
- Procedures utilized in accomplishing assigned tasks;
- The state of records which document the work performed; and
- Occurrences which suggest improper or unethical conduct.

10.3.2 GENERAL REQUIREMENTS

The QAO or designee will normally conduct the subject audits. Any individual designated to perform an audit must be: 1) competent to perform the required evaluations; 2) not responsible for any of the activities to be evaluated; and 3) not responsible directly or indirectly to the supervisor of the section being audited.

Checklists are provided for both Technical and Internal Audits. The auditor must complete the header information at the time of the audit, including the person interviewed. Notations are to be made in every field in the 'OK' column as a way of notating the auditor addressed each point. NA, or simply a dash, is sufficient notation to indicate the item was addressed.

10.3.3 PERFORMANCE

The audit will be conducted following ARDL's SOP "Internal Audits". In addition to interviews with personnel and observation of matters appearing in that list, the inspector will critically evaluate overall operations in the section to identify any potential weaknesses in procedures.

Based on observations, appropriate notes will be handwritten on the checklist. These notes will be reviewed verbally with the section supervisor during a conference, which will complete the audit. The notes will also be used as the basis for the Corrective Action Report (CAR), if required.

Auditors must also remain alert for evidence of any kind of improper or unethical activity. Such evidence may take many different forms. Additional space has been added at the end of the second page of the technical audit checklist for notations regarding any these events or others which suggest that there has been unacceptable conduct by members of the staff.

10.3.4 REPORTING

Root Cause Investigation and CARs identifying the reason(s) for any deficiency and summarizing the actions needed will be completed. For each deficiency a root cause must be identified, a corrective action must be proposed, and a period of time allotted for completion of that action. If the report involves an event which casts doubt on the validity or correctness of reported results, the clients affected must be notified within the next five working days both verbally and in writing.

If the corrective actions required involve significant effort and/or time, the section supervisor will respond in writing to recommendations made in the report. The response will include a plan to implement the corrective action and a schedule for when it will be complete. All corrective actions required as a result of the audit must be completed within 30 days of the date of the written report unless a specific exception is granted. If future corrective actions not associated with the audit are contemplated, a date for final implementation will be included in the response.

10.3.5 CONFIRMATION

A follow-up inspection will be performed in sections where corrective actions were required. Using the CAR as a guide, the QAO (or the designee who performed the audit) will visit the area and determine first hand if: 1) the corrective actions have been implemented; and 2) the actions have effectively resolved the noted problem. If that is so, the QAO will initial and date the appropriate items in the report summary. If not, the QAO will address a memorandum to senior management describing the shortfall and ways in which the problem can be resolved.

10.3.6 DOCUMENTATION

The observations made during any internal audit are recorded as notes on a checklist. The items on the checklist specify the major items of interest which the auditor inspects during the assessment. The audit should consist of an interview of the employee regarding actual practice as well as review of written records of those practices. Space is provided for those notes on the checklist. Space is also provided for a checkmark when the all elements of a particular item appear to satisfy the applicable standards.

When a departure from accepted practice or method requirements is noted, corrective action is required. The root cause for the excursion must be identified on the Root Cause Investigation Report and the specific activities required to resolve the difficulty described. The individual or individuals charged with responsibility for performing the required action(s) must be identified and a time line for completion must be estimated.

10.4 PERFORMANCE AUDITS

Performance audits consist of: 1) analysis of blind samples using prescribed methods; and 2) evaluation of laboratory control charts. The purpose of these audits is to demonstrate that, while using standard procedures and the equipment and facilities available on an everyday basis, the laboratory staff can accurately determine the true concentration of analytes(s) in samples with satisfactory accuracy and precision.

10.4.1 PE SAMPLES – APPROVED PROVIDERS

Two sets of PE samples in soil and water matrices are received on an approximately semi-annual basis from a supplier approved by an authorized accrediting body. The samples are prepared and analyzed following the procedures specified in the applicable methods. Standard data packages are prepared and the results are reported electronically to the provider.

On receipt of the required data, the PE sample provider evaluates the analytical data and sends a copy of his evaluation report to ARDL and the accrediting bodies designated by ARDL.

If the results reported are outside the acceptable range, the cause for the unacceptable values is identified by review of preparative and analytical records and a corrective action report describing the event is completed. If the incorrectly reported value(s) affects accreditation a remedial PE is obtained, analyzed and the result is reported as described above.

10.4.2 INTERNALLY PREPARED PE SAMPLES

In the past, evaluation of single blind PE samples prepared by the QAO (or a designee) has been utilized in support of: 1) internal investigations initiated when unacceptable results are obtained on external PE samples; 2) development of revised analytical/preparative methods; or 3) studies relative to the acceptability of proposed or recently adopted corrective action(s). The custom has fallen into disuse, however, and when need for such samples has arisen QA materials from accredited vendors have been utilized. If it seems appropriate in the future, however, the procedure will be revitalized.

In practice samples are prepared by a qualified analyst using certified solutions containing a single analyte or a mixture of analytes. The analyst supplies the QAO with a documented record of the sample(s) and the QAO distributes them for analysis to the appropriate laboratory section. After analysis, the results are submitted to the QAO along with suitable records documenting the work. The data is then reviewed with the analyst who performed the evaluation, the analyst's supervisor, and cognizant management personnel to determine the course of subsequent activities.

10.4.3 CONTROL CHART REVIEW

Control charts showing the results obtained on laboratory control samples, matrix spikes and sample duplicates are generated by electronic transfer of LIMS data to plotting software (see SOP entitled “Control Charts”). The charts are maintained for all methods performed in the laboratory. Both section supervisors and the QAO regularly review these charts and assess overall performance on methods used routinely.

Particular note is made of trends in the data, the frequency of excursions of results outside warning and / or control limits and other significant features of the charts. When the review indicates that a problem may be developing or has developed, corrective action is taken to resolve the difficulty.

10.5 METHOD AUDITS

Questions may arise relative to the accuracy or precision of values determined using a specific analytical method. Method audits are preformed to resolve those questions.

10.5.1 PERFORMANCE

A QC sample of known concentration is obtained from an approved vendor or the QAO prepares a sample or series of samples containing known concentration(s) of one or more of the standard analyte(s) determined by the subject method. Dependent on circumstances, laboratory personnel may or may not be advised of origin of the samples. Sample preparation, analysis and reporting proceed in the standard manner.

10.5.2 REPORTING

After analysis and reporting is complete, the QAO evaluates the data collected and, within 10 working days of completing the study, advises management and technical personnel of the results. In the event reported values are outside the window of acceptable accuracy, CARs are prepared which identify the probable cause(s) for the error and specify the actions to be taken to prevent a recurrence.

10.6 QUALITY SYSTEMS AUDITS

A quality system audit involves critical examination of activity in specific areas and the status of the records documenting that activity. Dependent on the nature of the activity under evaluation they may involve only review of the available written records or review of the records coupled with an interview of staff members responsible for those records. The QAO will perform the audit.

10.6.1 PERFORMANCE

The audit will be conducted using the quality system audit checklist. In addition to observation of matters appearing in that list, the inspector will critically evaluate overall operations in the section to identify any potential weaknesses in procedures which may result in future problems. The auditor must be alert for signs which suggest inappropriate or unethical activity. If weaknesses are noted, a memorandum regarding the matter is circulated to personnel. The memorandum requests that proposed suggestions for preventive action be submitted to senior management within 30 days.

Appropriate notes based on observations made during the audit will be handwritten on the checklist. To complete the first phase of the audit, those notes will be reviewed verbally with at least the responsible supervisor.

10.6.2 REPORTING

A copy of the checklist will be retained on file for at least five years. A CAR summary summarizing the actions needed and leaving space for notations of the date the action was implemented, by whom and the date that implementation was confirmed will be prepared as needed. If the corrective actions required involve significant effort and/or time the section supervisor will respond in writing to recommendations made in the report. The response will include a plan to implement the corrective action and a schedule for when it will be complete. All corrective actions required as a result of the audit must be completed within 30 days of the date of the written report unless a specific exception is granted.

10.6.3 MANAGEMENT REVIEWS

Management reviews of various elements of the quality system are performed by two or more members of senior management at irregular intervals throughout the calendar year. At least annually, however, the overall state of the system is evaluated critically by the entire senior management team. The procedures associated with these reviews are described in the most recent version of the SOP document entitled “Senior Management Review”.

10.6.4 DOCUMENT CONTROL

Review of distribution lists for all controlled documents for accuracy and completeness is performed. That review includes ensuring that the documents have been updated as required and that the locations specified for those documents are correct. The provisions for storage and filing of data and confidential documents for customers are examined to ensure that they are adequate and in compliance.

10.6.5 SUBCONTRACTING

Documented evidence which demonstrates accreditation equivalent to ARDL or at a level acceptable to the client must be on record at ARDL for all outside laboratories selected to receive samples for analysis. That documentation is reviewed for completeness and applicability to data reported to the client.

10.6.6 PURCHASING

Documented evidence must be on file that shows that all reagents, standards and materials affecting the quality of analytical data are ordered, received and stored in accordance with the provisions of ARDL’s SOP for each methodology of interest as well as the SOP entitled “Purchase of Materials”. That evidence is reviewed for completeness and accuracy.

10.7 INTERNAL AUDIT SCHEDULING

Internal technical audits will be performed in the first calendar quarter of the year. Internal audit of the quality system will be performed in the second calendar quarter along with the internal technical audit of any remaining area. All internal audits will be completed before the end of the third calendar quarter of the year.

11.0 QUALITY IMPROVEMENT

ARDL’s management is fully committed to generating and reporting environmental data of known and documented quality as well as providing clients with service which is unsurpassed in the environmental field. To achieve that goal, senior management has implemented a system which; provides clients with excellent quality products and service; is continuously monitored to identify ways it may be improved; and is zealously supported by all levels of the staff.

The ultimate objective of ARDL's quality system is to be certain the technical, administrative and business procedures are always performed using the highest levels of ethics and responsible professionalism. Procedures are in place to measure the overall quality of performance through improved record keeping, better report writing, enhanced sample handling and similar considerations. All of these help ensure that the data produced will withstand legal scrutiny, promote data integrity, identify training needs and detect weak methodology so that system goals are attained.

The quality system plan has been developed and implemented and the details of the system plan have been communicated to all staff members. Every one is charged with responsibility for: 1) evaluating ways in which they perform their daily work so that changes can be identified which may enhance product quality, 2) isolate potential sources of non-conforming work, 3) improve response time to client requests, 4) effect a reduction in labor or material costs or 5) otherwise raise the standard of services provided. When an instance for such an improvement is recognized, a plan for preventive action is developed and implemented and records kept which demonstrate whether or not the action taken achieved the desired end. Since the system was put in practice some years ago, it has served as a platform for continuous improvement in company operations.

Should an occasion arise where internal data review indicates that work is being or has already been performed which does not conform to policies or procedures or to the specifications for the work imposed by the customer, the following steps will be taken by the QAOs.

1) Collection of data will be suspended immediately to forestall acquisition of additional non-conforming data;
2) The employee and the employee's supervisor will be consulted, the reasons for the non-conformance will be established and suitable corrective action will be identified;
3) The usability and significance of results obtained will be evaluated;
4) If it appears that the quality of the data may be affected in any way the customer will be advised of the problem;
5) As directed by the customer, either: a) the work will continue as performed previously; b) the remainder of the work will be completed after implementing appropriate corrective action; or
6) Corrective action will be implemented and rework of all previously completed tasks will be performed. This could include resampling and reanalysis of environmental samples.

The event, the actions taken and the effect of those actions will be described in detail in the report submitted to the customer.

12.0 LOCATION

This document is stored on ARDL's LAN as a Microsoft word document at:

M:\SOP\Qual Mgmt Plan\ARDL QMP - Revision 1.3 041119.doc